IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT INFRINGEMENT LITIGATION	))))	C.A. No. 05-356-KAJ (consolidated)

NOTICE OF DEPOSITION AND SUBPOENA OF MUTUAL PHARMACEUTICAL COMPANY, INC. PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 45

PLEASE TAKE NOTICE that, pursuant to Rule 45 of the Federal Rules of Civil Procedure, plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P. and Synaptech, Inc. (collectively, "Janssen") will take the deposition upon oral examination of Mutual Pharmaceutical Company, Inc., at the offices of Esquire Deposition Services, Four Penn Center Plaza, Suite 1210, 1600 JFK Boulevard, Philadelphia, Pennsylvania 19103, beginning at 9:00 A.M. on June 13, 2006.

NOTICE IS FURTHER GIVEN THAT the deposition will be recorded stenographically through instant visual display of testimony (real-time), by certified shorthand reporter and notary public or such other person authorized to administer oaths under the laws of the United States, and shall continue from day to day until completed. This deposition will be videotaped.

NOTICE IS FURTHER GIVEN THAT pursuant to the Federal Rules of Civil Procedure, Janssen will serve upon Mutual Pharmaceutical Company, Inc. a Subpoena in a Civil Case. Attached hereto as Exhibit A is a true and correct copy of that Subpoena.

ASHBY & GEDDES

/s/ Tiffany Geyer Lydon

Steven J. Balick (I.D. #2114)
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Dated: May 26, 2006

169696.1

EXHIBIT A

A088 Subpoena in a Civil Case

Issued by the

United States District Court

EASTERN DISTRICT OF PENNSYLVANIA

IN RE: '318 PATENT INFRINGEMENT LITIGATION

SUBPOENA IN A CIVIL CASE

Case Number:[1] C.A. No. 05-356-KAJ (consolidated)
(District of Delaware)

TO: Mutual Pharmaceutical Company, Inc.
1100 Orthodox Street
Philadelphia, PA 19124-0

☐ YOU ARE COMMANDED to appear in the Unites States District court at the place, date, and time specified below to testify in the above case.

PLACE OF TESTIMONY	COURTROOM
	DATE AND TIME

☒ YOU ARE COMMANDED to appear at the place, date, and time specified below to testify at the taking of a deposition in the above case. Please See Schedule A Attached

PLACE OF DEPOSITION Recording Method: By stenographer and videotape	DATE AND TIME
Esquire Deposition Services, Four Penn Center Plaza, Suite 1210, 1600 JFK Boulevard, Philadelphia, Pennsylvania, 19103	June 13, 2006, 9:00 AM EST

☐ YOU ARE COMMANDED to produce and permit inspection and copying of the following documents or objects at the place, date, and time specified below (list documents or objects): Please See Schedule B Attached

PLACE	DATE AND TIME

☐ YOU ARE COMMANDED to permit inspection of the following premises at the date and time specified below.

PREMISES	DATE AND TIME

Any organization not a party to this suit that is subpoenaed for the taking of a deposition shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify. Federal Rules of Civil Procedure, 30(b)(6).

ISSUING OFFICER'S SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OR DEFENDANT)	DATE AND TIME
Attorney for Plaintiffs Janssen Pharmaceutica N.V., Janssen L.P., and Synaptech, Inc.	May 26, 2006
ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER Tiffany Geyer Lydon Ashby & Geddes 222 Delaware Avenue, 17th Floor Wilmington, DE 19899 Tel: 302-654-1888	

(See Rule 45, Federal Rules of Civil Procedure, Parts C&D on next page)

[1] If action is pending in district other than district of issuance, state district under case number.

PROOF OF SERVICE

DATE PLACE

SERVED

SERVED ON (PRINT NAME) MANNER OF SERVICE

SERVED BY (PRINT NAME) TITLE

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on _____
DATE

_____
SIGNATURE OF SERVER

_____
ADDRESS OF SERVER

Rule 45, Federal Rules of Civil Procedure, Parts C&D

(c) PROTECTION OF PERSONS SUBJECT TO SUBPOENAS.

(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction which may include, but is not limited to, lost earnings and reasonable attorney's fee.

(2)(A) A person commanded to produce and permit inspection and copying of designated books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for deposition, hearing or trial.

(2)(B) Subject to paragraph (d)(2) of this rule, a person commanded to produce and permit inspection and copying may, within 14 days after service of subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to inspection or copying of any or all of the designated materials or of the premises. If objection is made, the party serving the subpoena shall not be entitled to inspect and copy materials or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production. Such an order to comply production shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection and copying commanded.

(3) (A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it

(i) fails to allow reasonable time for compliance,
(ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to the provisions of clause (c)(3)(B)(iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held, or
(iii) requires disclosure of privileged or other protected matter and no exception or waiver applies, or
(iv) subjects a person to undue burden

(3)(B) If a subpoena

(i) requires disclosure of a trade secret or other confidential research, development, or commercial information, or
(ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or
(iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena, or, if the party in who behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

(d) DUTIES IN RESPONDING TO SUBPOENA.

(1) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.

(2) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

SCHEDULE A

DEFINITIONS

1. As used herein, "the '318 patent" shall mean United States Patent No. 4,663,318.

2. As used herein, "ANDA" shall mean Abbreviated New Drug Application Number 77-586.

3. As used herein, "Plaintiffs" refers to Janssen Pharmaceutica N.V., Janssen, L.P. and Synaptech, Inc., either individually or collectively.

4. As used herein, "You," "Your," or "Yours," shall mean Mutual Pharmaceutical Company, Inc., Mutual Pharmaceutical Company, Inc.'s corporate predecessors and past or present subsidiaries, affiliates, divisions, departments, officers, directors, principals, agents, employees and any individuals or entities that at any time have acted or purported to act on behalf of Mutual Pharmaceutical Company, Inc. or its successors.

TOPICS

1. The notice You sent to Plaintiffs on April 22, 2005, attached hereto as Exhibit 1.

2. Your patent certification regarding the '318 patent in connection with ANDA No. 77-586.

EXHIBIT 1

United Research Laboratories, Inc.
Mutual Pharmaceutical Company, Inc.
1100 Orthodox Street
Philadelphia, PA 19124
215-288-6500
www.urlmutual.com

April 22, 2005

Via Registered Mail – Return Receipt Requested

Attention: President
Janssen Pharmaceutica N.V.
Turnhoutseweg 30
B-2340 Beers Belgium

Re: Mutual Pharmaceutical Company
Notice of Paragraph IV Certification
U.S. Patent No. 6,099,863 and U.S. Patent No. 6,358,527
Galantamine Hydrobromide

Dear Sir or Madam:

Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act (the "Act") and 21 C.F.R. §§ 314.94 and 314.95, Mutual Pharmaceutical Company ("Applicant" or "Mutual") hereby provides the following information concerning U.S. Patent No. 6,099,863 ("the '863 patent") and U.S. Patent No. 6,358,527 ("the '527 patent"):

1. Applicant has submitted to the United States Food and Drug Administration ("FDA") an Abbreviated New Drug Application ("ANDA") which contains any required bioavailability or bioequivalence data or information, and which seeks approval to engage in the commercial manufacture, use and sale of galantamine hydrobromide; oral ("Mutual's proposed product") before the expiration dates of the '863 patent and the '527 patent.

2. The ANDA number is ANDA 77-586.

3. The established name as defined in § 352(e)(3) of the Act of the proposed drug product is "galantamine hydrobromide tablet; oral; 4 mg base," "galantamine hydrobromide tablet; oral; 8 mg base," and "galantamine hydrobromide tablet; oral; 12 mg base."

4. The active ingredient of the proposed drug product is galantamine hydrobromide; the strengths are 4 mg, 8 mg and 12 mg, and the dosage form is a tablet.

Janssen Pharmaceutica
April 22, 2005

5. The '863 patent and the '527 patent were identified to the FDA pursuant to 21 U.S.C. § 355(b)(1). The expiration date of both patents is June 6, 2017. No valid claim of the '863 patent and/or the '527 patent will be infringed by the manufacture, use or sale of the product for which the application has been submitted by Applicant.

6. Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act (the "Act") and 21 C.F.R. §§ 314.94 and 314.95, a detailed statement of the factual and legal bases of Applicant's opinion is attached as Exhibit 1. The detailed statement is being made in accordance with the Act, and Applicant does not waive any attorney-client privilege in providing this statement.

An Offer of Confidential Access to ANDA 77-586, in accordance with 21 U.S.C. § 355(j)(5)(C)(i)(III), is attached as Exhibit 2.

For the attached reasons, the '863 patent and the '527 patent will not be infringed, either literally or under the doctrine of equivalents, by the manufacture, use, sale or offer of sale of Mutual's proposed product. Mutual expressly reserves the right to challenge the validity and enforceability of the '863 patent and the '527 patent and/or any assertion of infringement that Janssen Pharmaceutica ("Janssen") might make on new, other or further grounds should such grounds become apparent during any ensuing litigation between the parties.

Sincerely,

Brendan Magrab
Vice-President, Intellectual Properties
Mutual Pharmaceutical Company
1100 Orthodox Street
Philadelphia, PA 19124
1 (800) 523-3684
1 (215) 288-6559 (fax)

Janssen Pharmaceutica
April 22, 2005

EXHIBIT 1:

FACTUAL AND LEGAL BASIS FOR NONINFRINGEMENT OF THE '863 PATENT AND THE '527 PATENT

I. Mutual's Proposed Product

Mutual's ANDA seeks approval to market tablets ("Mutual's proposed product") that are "bioequivalent" to Janssen's REMINYL® galantamine hydrobromide tablet product. Mutual's proposed product will be labeled in accordance with the currently approved uses contained in the REMINYL® label, i.e. treatment of mild to moderate dementia of the Alzheimer's type.

Mutual's proposed product will be manufactured in 4 mg, 8 mg and 12 mg dosages, to include the following ingredients:

Components of Mutual's Proposed Product

INGREDIENTS
Galantamine HBr
Lactose Monohydrate, NF (Fast Flo)
Anhydrous Lactose, NF DT
Crospovidone, NF (Polyplasdone XL)
Povidone, USP (Plasdone K 29/32)
Magnesium Stearate, NF
Opadry II (different colors)
Carnauba wax

Mutual's proposed product contains only one type of disintegrant, Polyplasdone XL (crospovidone NF), which is an insoluble cross-linked polymer.

II. U.S. Patent No. 6,099,863

A. The Claimed Invention of the '863 patent

The '863 patent relates to tablets comprising galanthamine hydrobromide and a pharmaceutically acceptable carrier. Specifically, the patent discloses a carrier comprising "a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent, and an insoluble or poorly soluble cross-linked polymer disintegrant." The '863 patent issued with 10 claims, of which claim 1 is the only independent claim. Independent claim 1 reads as follows:

Janssen Pharmaceutica
April 21, 2005

1. A tablet comprising as an active ingredient a therapeutically effective amount of galanthamine hydrobromide (1:1) and a pharmaceutically acceptable carrier, wherein said carrier comprises a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent, and an insoluble or poorly soluble cross-linked polymer disintegrant.

B. Mutual's Proposed Product Will Not Infringe the Claims of the '863 Patent[1]

An infringement analysis of patent claims is performed in two steps. First, the claims must be interpreted in view of the specification, prosecution history, and other claims, to establish their meaning and scope. Markman v. Westview Instruments, Inc., 116 S. Ct. 1384 (1996). After a claim has been properly interpreted, infringement is determined by comparing the claim with the so-construed claim. If each limitation of the so-construed claim is found in the product or process, there is literal infringement.

Even if the product does not literally infringe, infringement may be found under the doctrine of equivalents. The Supreme Court in Graver Tank & Mfg. Co. v. Linde Air Products Co., 339 U.S. 605 (1950) set out the modern contours of the doctrine and more recently visited the subject in Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 18 (1997), in an "endeavor to clarify the proper scope of the doctrine."

The doctrine of equivalents must be applied to individual elements of a claim and not to the invention as a whole. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 117 S. Ct. 1040, 1049 (1997). Even if equivalency between each element of the accused product and each element of the claimed invention exists, infringement will not be found if: (1) prosecution history estoppel applies; or (2) a hypothetical patent claim, sufficient in scope to literally cover the accused product, is not patentable over the prior art. Wilson Sporting Goods Co. v. David Geoffrey & Associates, 904 F.2d 677 (Fed. Cir.), *cert. denied*, 498 U.S. 992 (1990). As such, the prior art must be examined to assure that the range of equivalents asserted by the patent holder does not encroach upon subject matter in the prior art.

Under the doctrine of prosecution history estoppel, a patentee can be precluded from recapturing through equivalents claim coverage given up by argument or amendment during patent prosecution. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 564 (Fed. Cir. 2000) (citing Pharmacia & Upjohn Co. v.

[1] In considering infringement, if a product or method avoids infringement of a claim, it also avoids infringement of all claims which depend from that claim, because the dependent claims include the limitations of the claim which is not infringed under 35 U.S.C. § 112, fourth paragraph. *See, e.g.*, Wahpeton Canvas Co. v. Frontier, Inc., 870 F.2d 1546, 1552 n.9 (Fed. Cir. 1989).

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April 22, 2005

Mylan Pharms., Inc., 170 F.3d 1373, 1376-77 (Fed. Cir. 1999)) (Festo I), *aff'd in part, rev'd in part and remanded*, 122 S.Ct. 1831 (2002) (Festo II), *on remand*, 344 F.3d 1359

(Fed. Cir. 2003) (Festo III). The estoppel applies to claim amendments made to overcome rejections based on the prior art or any formal rejections that narrow the patent claims. Festo II at 1839-40.

Where the record does not reveal whether the subject matter was surrendered to avoid the prior art or for unrelated reasons, a rebuttable presumption arises that the amendment and/or argument was made to avoid the prior art and, thus, prosecution history estoppel bars the application of the doctrine of equivalents for that element. Warner-Jenkinson, *supra*, at 33. Festo II upheld this requirement, and added an additional burden on the patentee to show that the amendment does not surrender the particular equivalent in question. Festo II at 1842. The Supreme Court noted that "[A] patentee's decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim." Id. The patentee may only overcome this presumption by showing that, at the time of the amendment, one skilled in the art could not reasonably have been expected to have drafted a claim that would have literally encompassed the alleged equivalent (i.e., the alleged equivalent was not foreseeable, that the rationale underlying the narrowing amendment bore no more than a tangential relation to the equivalent in question, or that there was "some other reason" suggesting that the patentee could not reasonably have been expected to have described the alleged equivalent). Festo III at 1368 (citing Festo II at 1831).

The Federal Circuit has indicated that, when a patent applicant argues that a set of limitations distinguish a claim from the prior art, prosecution history estoppel may attach to these limitations collectively. Read Corp. v. Portec, Inc., 970 F.2d 816, (Fed. Cir. 1992). In addition, once an argument or amendment is made regarding a claim term so as to create an estoppel, the estoppel will also apply to the same term used in other claims. Southwall Technologies v. Cardinal IG Co., 54 F.3d 1570 (Fed. Cir. 1995). Further, the estoppel will apply even if those other claims originally contained the narrowing limitation added to the amended claims. Glaxo Wellcome, Inc. v. Impax Laboratories, Inc., 356 F.3d 1348, 1356-1357 (Fed. Cir. 2004). It is also well-settled that the arguments and amendments in the prosecution history of one patent in a chain of patents may be relied upon for estoppel in a later-issued patent in the chain. Jonsson v. Stanley Works, 903 F.2d 812, 818 (Fed. Cir. 1990).

Janssen Pharmaceutica
April 22, 2005

1. Mutual's Proposed Product Will Not Literally Infringe the Claims of the '863 Patent

As noted above, claim 1 is the only independent claim of the '863 patent. Further, claim 1 is a product claim. Thus, in order to determine whether Mutual's proposed product literally infringes claim 1 of the '863 patent, a comparison must be made between the product and claim 1.

Claim 1 requires that the tablet or product have "a spray dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent and an insoluble or poorly soluble cross-linked polymer disintegrant" (emphasis added).

Mutual's proposed product does not contain microcrystalline cellulose, much less a (75:25) ratio of lactose monohydrate and microcrystalline cellulose, as required by claim 1.

As all of the claims of the '863 patent require microcrystalline cellulose, there is no direct infringement of any claim of the '863 patent by Mutual's proposed product.

2. Mutual's Proposed Product Will Not Infringe the Claims of the '863 Patent Under the Doctrine of Equivalents

The finding that Mutual's proposed product will not literally infringe the claims of the '863 patent requires a comparison of the product with the claims under the doctrine of equivalents. An analysis is required to determine whether the differences between Mutual's proposed product and the claimed composition are insubstantial and whether the range of the permissible equivalents could properly cover the manufacture, use, offer of sale, or sale of Mutual's proposed product.

The '863 patent specification clearly requires the tablet to contain "a particular diluent containing a disintegrant, and a second disintegrant." See column 2, lines 65-67 of the '863 patent. Further, in the prosecution history, the Examiner required that the claims be amended to reflect the specific type of (second) disintegrant used in the tablets. See the October 15, 1999 Office Action. In response, Applicants amended claim 1 to require "an insoluble or poorly insoluble cross-linked polymer disintegrant which provides the required dissolution specification of 80% after 30 minutes" (internal quotations omitted). See January 18, 2000 Amendment, page 2, last paragraph. Thus, it is imperative that the tablet claimed in the '863 patent contain two types of disintegrants:

(1) a first disintegrant within a particular diluent; and
(2) a second, insoluble or poorly soluble cross-linked polymer disintegrant having a large coefficient of expansion.

The formulation for Mutual's proposed product only contains a single type of disintegrant, Polyplasdone XL (Crospovidone, NF) (see above Table). "Microcrystalline cellulose," which is required by the claims of the '863 patent, is not found within the formulation for Mutual's proposed product, nor is there an equivalent element present. No other type of disintegrant is present in the formulation for Mutual's proposed product. Thus, as each and every element of the '863 patent, or its equivalent, is not found within Mutual's proposed product, as a matter of law, Mutual's proposed product cannot infringe the claims of the '863 patent under the doctrine of equivalents.

Moreover, the doctrine of prosecution history estoppel applies to preclude the '863 patentees from extending the range of equivalents to encompass Mutual's proposed product. In addition, the prior art would necessarily limit any extension of the claims of the '863 patent to encompass Mutual's proposed product.

In the Office Action dated October 15, 1999, claims 1, 3-5 and 7-10 were rejected by the Examiner under 35 U.S.C. § 112, first paragraph, for lack of enablement. In the subsequent Amendment filed on January 18, 2000, the '863 patent Applicants amended claim 1 to require "an insoluble or poorly insoluble cross-linked polymer disintegrant which provides the required dissolution specification of 80% after 30 minutes" (internal quotations omitted).[2] See January 18, 2000 Amendment, page 2, last paragraph. In light of this Amendment, the application was allowed.

As the '863 patent Applicants amended claim 1 to require a particular type of (second) disintegrant distinct from microcrystalline cellulose, the '863 patent Applicants effectively disclaimed any galantamine hydrobromide tablets containing a single type of disintegrant. The '863 patent Applicants relied on the limitation with respect to the particular (second) required disintegrant, "an insoluble or poorly soluble cross-linked polymer disintegrant" (claim 1) in addition to the claimed microcrystalline cellulose, to distinguish over the prior art formulations for galantamine hydrobromide. Thus, it is presumed under Festo II, the '863 patent Applicants disclaimed any territory wherein the tablet or product contains only a single disintegrant.

The '863 patent Applicants are not able to overcome this presumption, because the alleged equivalent (i.e., Mutual's proposed product, containing a single type of disintegrant) was foreseeable at the time of the amendment, as similar products were shown in the prior art. In fact, the specification discloses that such alleged equivalents

[2] Under *Festo II*, arguments and claim amendments in response to an enablement rejection under 35 U.S.C. § 112, first paragraph, result in prosecution history estoppel.

were rejected by the Applicants of the '863 patent. The specification states the following:

> Initial experiments started out using either lactose anhydrous or lactose monohydrate as a diluent, and either powdered cellulose or microcrystalline cellulose as disintegrant (see tablet formulations F1 and F2 in the Experimental Part). ... the tablets formulations F1 and F2 did not comply at Stage 1 with the dissolution specification of Q=80% after 30'. In order to solve the perceived problems, the diluent was substituted for a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25), commercially available as Microcelac™. ... The dissolution specification was not met, however, unless a disintegrant having a large coefficient of expansion was employed, more in particular, if an insoluble or poorly soluble cross-linked polymer as, for example, crospolyvidone or croscarmellose was employed.

See column 3, lines 10-32 of the '863 patent. Thus, the '863 patent Applicants are estopped from claiming that a galantamine hydrobromide tablet containing a single type of disintegrant, i.e. Mutual's proposed product, infringes the claims of the '863 patent under the doctrine of equivalents.

As noted above, Mutual's proposed product has only one type of disintegrant, which falls squarely within the galantamine hydrobromide tablets disclaimed by the Applicants of the '863 patent.

Further, in the Notice of Allowability of March 11, 2000, the Examiner indicated in his "statement of reasons for allowance" that:

> ... the prior art does not show nor fairly suggest applicants composition comprised of galantamine hydrobromide (1:1) and a particular pharmaceutical carrier. The particular carrier combination of a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent and an insoluble or poorly soluble cross-linked polymer disintegrant enables the fast distribution of said tablet.

Thus, the Examiner explicitly indicated in the Notice of Allowance that the recitation of both the specific carrier and disintegrant in claim 1 were considered essential to the allowance and issuance of the '863 patent. This statement confirms that the Examiner considered the presence of microcrystalline cellulose to be necessary for

patentability. Thus, the '863 patent is estopped from recapturing products that do not include microcrystalline cellulose, such as Mutual's proposed product.

For at least these reasons, Mutual's proposed product will not infringe the claims of the '863 patent under the doctrine of equivalents.

III. U.S. Patent No. 6,358,527

A. The Claimed Invention of the '527 Patent

The '527 patent relates to a method of treating dementia, mania or nicotine dependence by administering a tablet comprising galanthamine hydrobromide and a pharmaceutically acceptable carrier. The '527 patent also relates to a fast dissolving galanthamine hydrobromide tablet made by a particular process of dry blending and compressing with optional steps of mixing a lubricant, and/or film-coating the compressed tablet. Specifically, the patent discloses that the tablets require "a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent." The '527 patent issued with 6 claims. Independent claims 1 and 6 read as follows:

> 1. A method of treating a disorder selected from dementia, mania or nicotine dependence in a patient in need thereof comprising administering to the patient a tablet comprising as an active ingredient a therapeutically effective amount of galanthamine hydrobromide (1:1) and a pharmaceutically acceptable carrier, wherein said carrier comprises a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent, and an insoluble or poorly soluble cross-linked polymer disintegrant.
>
> 6. A fast-dissolving galanthamine hydrobromide (1:1) tablet made by (i) dry blending the active ingredient, an insoluble or poorly soluble cross-linked polymer disintegrant and an optional glidant with a diluent comprising a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25); (ii) optionally mixing a lubricant with the mixture obtained in step (i); (iii) compressing the mixture obtained in step (i) or in step (ii) in the dry state into a tablet; and (iv) optionally film-coating the tablet obtained in step (iii).

Janssen Pharmaceutica
April 22, 2005

B. Mutual's Proposed Product Will Not Infringe the Claims of the '527 Patent[3]

1. Mutual's Proposed Product Will Not Literally Infringe the Claims of the '527 Patent

As noted above, claims 1 and 6 are the only independent claims of the '527 patent. Claim 1 is a method of treatment claim and claim 6 is a product by process claim. In order to determine whether Mutual's galantamine hydrobromide tablets literally infringe claims 1 or 6 of the '527 patent, a comparison must be made between Mutual's product and process, and the product used in the method of claim 1 and created by the process of claim 6.

Claim 1 requires that the tablet or product used in the method of treatment have "a spray dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent and an insoluble or poorly soluble cross-linked polymer disintegrant" (emphasis added). Meanwhile, claim 6 of the '527 patent requires the tablet or product to be made by a process which includes "dry blending the active ingredient, an insoluble or poorly soluble cross-linked polymer disintegrant and an optional glidant with a diluent comprising a spray dried mixture of lactose monohydrate and microcrystalline cellulose (75:25)" (emphasis added).

Mutual's proposed product does not contain microcrystalline cellulose, much less a (75:25) ratio of lactose monohydrate and microcrystalline cellulose, as required by the claims of the '527 patent.

As all of the claims of the '527 patent require microcrystalline cellulose, there is no direct infringement of any claim of the '527 patent by Mutual's proposed product.

2. Mutual's Proposed Product Will Not Infringe the Claims of the '527 Patent Under the Doctrine of Equivalents

The finding that Mutual's proposed product will not literally infringe the claims of the '527 patent requires a comparison of the tablets with the claims under the doctrine of equivalents. An analysis is required to determine whether the differences between Mutual's proposed product and the claimed composition are insubstantial and whether the range of the permissible equivalents could properly cover the manufacture, use, offer of sale, or sale of Mutual's proposed product.

The '527 patent specification clearly requires the tablet to contain "a particular diluent containing a disintegrant, and a second disintegrant." See column 3, lines 1-3 of

[3] The law regarding patent infringement is provided in Section II.B., *supra*.

the '527 patent. Further, in the prosecution history of the parent '863 patent and the '527 patent, the Examiner required that the claims be amended to reflect the specific type of (second) disintegrant used in the tablets. See the October 15, 1999 Office Action in the prosecution history of the '863 patent, and the May 22, 2001 Office Action in the prosecution history of the '527 patent. Applicants responded to both Office Actions by amending the claims (claim 16 of the '527 patent and claim 1 of the '863 patent) to require "an insoluble or poorly insoluble cross-linked polymer disintegrant." See the August 22, 2001 Amendment, page 3, lines 5-10 in the prosecution history of the '527 patent and the January 18, 2000 Amendment, page 2, last paragraph, in the prosecution history of the '863 patent.

As issued claims 1 and 6 (claims 11 and 16 during prosecution) of the '527 patent require "an insoluble or poorly soluble cross-linked polymer disintegrant," it is imperative that the tablet claimed in the '527 patent contain two types of disintegrant:

(1) a first disintegrant within a particular diluent; and
(2) a second, insoluble or poorly soluble cross-linked polymer disintegrant having a large coefficient of expansion.

The formulation of Mutual's proposed product only contains a single type of disintegrant, Polyplasdone XL (Crospovidone, NF) (see above Table). "Microcrystalline cellulose," which is required by the claims of the '527 patent, is not found within the formulation for Mutual's proposed product, nor is there an equivalent element present. No other type of disintegrant is present in the formulation for Mutual's proposed product. Thus, as each and every element of the '527 patent, or its equivalent, is not found within Mutual's proposed product, as a matter of law, Mutual's proposed product does not infringe the claims of the '527 patent under the doctrine of equivalents.

Moreover, the doctrine of prosecution history estoppel applies to preclude the '527 patentees from extending the range of equivalents to encompass Mutual's proposed product. In addition, the prior art would necessarily limit any extension of the claims of the '527 patent to encompass Mutual's product.

During prosecution of the application for the parent '863 patent, the Applicants amended claim 1 to require "an insoluble or poorly insoluble cross-linked polymer disintegrant which provides the required dissolution specification of 80% after 30 minutes" (internal quotations omitted) in response to a lack of enablement rejection under 35 U.S.C. § 112, first paragraph.[4] See January 18, 2000 Amendment, page 2, last paragraph, in the prosecution of the '863 patent. In light of this Amendment, the parent application was allowed and issued as the parent '863 patent.

[4] Under Festo II, arguments and claim amendments in response to an enablement rejection under 35 U.S.C. § 112, first paragraph, result in prosecution history estoppel.

Meanwhile, claim 6 of the '527 patent (claim 16 during prosecution) was amended by the Applicants "to include the limitation that the disintegrant is an insoluble or poorly soluble cross-linked polymer and the diluent comprises a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25)" in response to a lack of enablement rejection under 35 U.S.C. § 112, first paragraph. See August 22, 2001 Amendment, page 3, lines 5-10. In light of this Amendment and the filing of a Terminal Disclaimer over the '863 patent, the application was allowed and issued as the '527 patent.

As Applicants amended claim 1 of the parent '863 patent and claim 6 of the '527 patent to require a particular type of (second) disintegrant distinct from microcrystalline cellulose, the '527 patent Applicants effectively disclaimed any galantamine hydrobromide tablets containing a single type of disintegrant. The '527 patent Applicants relied on the limitation with respect to the particular (second) required disintegrant, "an insoluble or poorly soluble cross-linked polymer disintegrant" (claims 1 and 6) in addition to the claimed microcrystalline cellulose, to distinguish over the prior art formulations for galantamine hydrobromide and methods of treatment using such formulations. Thus, it is presumed under Festo II that the '527 patent Applicants disclaimed any territory wherein the tablet or product produced or utilized in a method of treatment contains only a single type of disintegrant.

The '527 patent Applicants are not able to overcome this presumption, because the alleged equivalent (i.e., Mutual's proposed product, containing a single type of disintegrant) was foreseeable at the time of the amendment, as similar product were shown in the prior art. In fact, the specification discloses that such equivalents were rejected by the Applicants of the '527 patent. The specification states the following:

> Initial experiments started out using either lactose anhydrous or lactose monohydrate as a diluent, and either powdered cellulose or microcrystalline cellulose as disintegrant (see tablet formulations F1 and F2 in the Experimental Part). ... the tablets formulations F1 and F2 did not comply at Stage 1 with the dissolution specification of Q=80% after 30'. In order to solve the perceived problems, the diluent was substituted for a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25), commercially available as Microcelac™. ... The dissolution specification was not met, however, unless a disintegrant having a large coefficient of expansion was employed, more in particular, if an insoluble or poorly soluble cross-linked polymer as, for example, crospolyvidone or croscarmellose was employed.

See column 3, lines 13-34 of the '527 patent. Thus, the '527 patent Applicants are estopped from claiming that a single type of disintegrant, i.e. Mutual's proposed product, infringes the claims of the '527 patent under the doctrine of equivalents.

As noted above, Mutual's proposed product has only one type of disintegrant, which falls squarely within the galantamine hydrobromide tablets disclaimed by the Applicants of the '527 patent.

For at least these reasons, Mutual's proposed product will not infringe the claims of the '527 patent under the doctrine of equivalents.

Janssen Pharmaceutica
April 22, 2005

EXHIBIT 2:

OFFER OF CONFIDENTIAL ACCESS TO APPLICATION

Mutual Pharmaceutical Company ("Mutual") hereby offers Janssen Pharmaceutica ("Janssen") confidential access to Abbreviated New Drug Application ("ANDA") No. 77-586 as required under 21 U.S.C. § 355(j)(5)(C)(i)(III). Mutual hereby stipulates that the following restrictions shall govern this Offer of Confidential Access to Application ("Offer") and any information or documents accessed, and/or the use and disposition of any information or documents accessed, under this Offer:

1. As stated by 21 U.S.C. § 355(j)(5)(C)(i)(III), "[a] request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract."

2. For purposes of the access and/or inspection, the application for ANDA No. 77-586, and any other accompanying documents and materials, shall be considered as containing Confidential Information.

3. As stated by 21 U.S.C. § 355(j)(5)(C)(i)(III), Confidential Information disclosed under this Offer shall be used only for the sole and limited purpose of evaluating possible infringement of U.S. Patent No. 6,099,863 ("the '863 patent") and/or U.S. Patent No. 6,358,527 ("the '527 patent"), the patents that are the subject of the certification under 28 U.S.C. § 355 (b)(2)(A)(iv) and shall not be disclosed by the recipient to any person or entity other than:

(a) Outside Counsel for Janssen and members and associates of counsel's law firms, and legal assistants and clerical employees of those firms actively engaged in evaluating possible infringement of the '863 patent and/or the '527 patent, the patents that are the subject of the certification under 28 U.S.C. § 355 (b)(2)(A)(iv).

(b) In-house counsel and business representatives of Janssen who are actively engaged in evaluating possible infringement of the '863 patent and/or the '527 patent, the patents that are the subject of the certification under 28 U.S.C. § 355 (b)(2)(A)(iv). With regard to in-house counsel, it is expressly required that these individuals shall be acting in their capacity as lawyers and not as business advisors, and that no Confidential Information will be used in connection with any business advice rendered by such in-house counsel to their clients nor revealed to non-lawyers employed by any party.

(c) Independent non-employee experts retained for the purpose of evaluating possible infringement of the patents that are the subject of the certification under 28 U.S.C. § 355 (b)(2)(A)(iv). Prior to gaining access to any Confidential Information acquired under the Offer, such experts must receive and read a copy of this Offer and agree to be bound thereby by executing an affidavit in the form attached hereto as Exhibit A.

(d) Such other persons upon whom Mutual expressly agrees in writing.

(e) Such other persons as a Court may approve after notice and hearing.

(f) A Court.

4. Prior to disclosure to any person designated pursuant to paragraph 3(c) hereof of the Confidential Information, such person shall be furnished with a copy of this Offer and shall be required to execute an affidavit in the format attached hereto as Exhibit A (or a substantially similar declaration) certifying that be or she has read this Offer, understands it and agrees to be bound by the terms thereof.

5. Mutual agrees to provide access to ANDA No. 77-586 upon the receipt of a request for access from Janssen. However, Mutual retains the right under 21 U.S.C. §

355(j)(5)(C)(i)(III) to redact the application for ANDA No. 77-586 to remove any information of no relevance to any issue of patent infringement.

6. Upon receipt of Confidential Information provided pursuant to this Offer, Janssen shall maintain such Confidential Information in a secure and safe area and shall exercise due and proper care with respect to the storage, custody and use of all Confidential Information. There shall be no reproduction of any Confidential Information except that, as required in the evaluation of possible infringement of the '863 patent and/or the '527 patent, copies, excerpts, or summaries may be shown or given to those persons authorized pursuant to paragraph 3 above. Except as otherwise provided above, all Confidential Information shall remain in the custody of the initial recipient of the Confidential Information.

7. In a reasonable time after a determination of possible infringement of the '863 patent and/or the '527 patent is made, preferably within sixty (60) days, all Confidential Information furnished pursuant to the terms of this Offer, any drawings related to and notes taken based on said Confidential Information, and all copies thereof, which are not in the custody of a Court, shall be returned to Mutual or destroyed (and certified under penalty of perjury as having been destroyed) by Janssen.

8. The restrictions set forth in the preceding Paragraphs shall not apply to Confidential Information which (a) is or becomes public knowledge not in violation of this Offer; (b) is from a third party lawfully possessing and lawfully entitled to disclose such information; or (c) is disclosed by a third party with the approval of Mutual.

9. Nothing contained in this offer shall restrict the use or disclosure of Confidential Information by Mutual.

Janssen Pharmaceutica
April 22, 2005

10. In the event anyone shall violate or threaten to violate any term of this Offer, Janssen agrees that Mutual may immediately apply to obtain injunctive relief against any such person violating or threatening to violate any of the terms of this Offer and, in the event Mutual shall do so, the respondent person subject to the provisions of this Offer shall not employ as a defense thereto the claim that Mutual possesses an adequate remedy at law. Further, the respondent person must agree to subject themselves to the personal jurisdiction of the United States District Court for the jurisdiction in which they reside for this purpose.

11. The obligation to maintain confidentiality embodied in this Offer shall survive the termination the evaluation of possible infringement of the '863 patent and/or the '527 patent and any related proceedings.

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Vice-President, Intellectual Properties
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1 (215) 288-6559 (fax)

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Title:_____

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Titusville, New Jersey 08560
609-730-2000
609-730-2323 (fax)

Name:_____

Title:_____

Janssen Pharmaceutica
April 22, 2005

5. I understand that any use of Confidential Information in any manner contrary to the provisions of the Offer may subject me to sanctions by a Court, and I hereby agree to subject myself to the personal jurisdiction of the United States District Court for the jurisdiction in which I reside for this purpose.

_____
Signature

Subscribed and sworn to before me, this ____ day of _____, 200__.

_____
Notary Public

My Commission Expires: _____

CERTIFICATE OF SERVICE

I hereby certify that on the 26th day of May, 2006, the attached **NOTICE OF DEPOSITION AND SUBPOENA OF MUTUAL PHARMACEUTICAL COMPANY, INC. PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 45** was served upon the below-named counsel of record at the address and in the manner indicated:

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/s/ *Tiffany Geyer Lydon*

Tiffany Geyer Lydon